

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO

DONNA HOGUE, et al.,

Plaintiffs,

VS.

PFIZER, INC., et al.,

Defendants.

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CASE NO. 2:10-CV-805

JUDGE MICHAEL WATSON

**PLAINTIFFS' RESPONSE TO BRAND DEFENDANTS'
MOTIONS FOR SUMMARY JUDGMENT**

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Plaintiffs Donna and James Hogue (“Plaintiffs”) file this response to Defendants Pfizer, Inc., Wyeth LLC, and Schwarz Pharma, Inc.’s (“Brand Defendants”) Motions for Summary Judgment, and would show the Court as follows:

I. PRELIMINARY STATEMENT

Brand Defendants ask the Court to treat this case like any other products case, in effect arguing that they cannot be held liable for the drug that Mrs. Hogue took because they did not manufacture the pills she consumed. Brand Defendants reference other decisions where courts, based on old case law, have followed this line of thought. The foundation case (*Foster*) has been implicitly overturned by the recent *Mensing* case from the U.S. Supreme Court – which held that that the brand name manufacturer (Brand Defendants in this case) is exclusively responsible for the content of the label for the pills Mrs. Hogue consumed.

After the passage of time, a brand name drug maker is likely to find its product being duplicated exactly and sold by other manufacturers as a “generic” drug. To bring a drug to market, a brand name drug maker must file a New Drug Application (“NDA”) and establish the safety and efficacy of a proposed drug before obtaining FDA approval, and the brand name drug maker has an *ongoing responsibility* to update safety information. The Hatch-Waxman Amendments and the *Mensing* decision require a generic manufacturer to rely on the NDA sponsor’s labeling, including all warning labels, when filing an Abbreviated New Drug Application (“ANDA”). Under this regulatory scheme, the brand name manufacturer knows that a generic drug must carry the *same warning* it created.

Plaintiffs’ claims with regard to Brand Defendants do not relate to the composition or manufacture of the metoclopramide Mrs. Hogue ingested, but rather focuses on the overt misrepresentations, the inaccurate and insufficient label information promulgated by Brand

Defendants and by which the drug was prescribed. Mrs. Hogue and her prescribing physicians relied on these misrepresentations made by Brand Defendants (and duplicated in the label by the generic manufacturer of the pills she consumed) in the decision to prescribe and consume the drug. Brand Defendants would prefer to characterize this as a “product liability” action against them, when in fact it is not. The Court is not being asked to rewrite Ohio products liability law or ignore fundamental principles. Instead, the Court is merely asked to apply fundamental law regarding fraud and misrepresentations made by the Brand Defendants. A brand name manufacturer may be held liable for injuries suffered by a patient who purchased a drug (generic or brand) if the injuries were foreseeably caused by negligent or intentional misrepresentations of the pharmaceutical company that induced the purchase and consumption of the drug.

II. FACTUAL BACKGROUND

Before marketing a prescription drug, a pharmaceutical manufacturer must obtain regulatory approval from the FDA. For the innovator drug, the innovator must submit a New Drug Application (“NDA”). 21 U.S.C. § 355(a)-(i). The innovator must prove both safety and efficacy of the drug through extensive laboratory and clinical trials. *Id.* § 355(b)(1)(F). The FDA will deny the NDA if the innovator does not provide, among other things, “adequate tests . . . to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling.” *Id.* § 355 (d)(1).

Once the NDA is approved, the innovator has the exclusive right to market the drug for a certain period of time. Once that exclusivity period has expired, other drug manufacturers may market generic versions of the innovator drug if such approval has been obtained.

As this Court is aware, the approval procedure for generic drugs was relaxed and abbreviated by the *Drug Price Competition and Patent Term Restoration Act of 1984* (commonly

known as the “Hatch-Waxman Amendments”), Pub. L. No. 98-417, 98 Stat. 1584 (1984). A generic manufacturer may choose to submit only an Abbreviated NDA, or “ANDA.” If this choice is made, then the generic manufacturer no longer has to submit independent evidence of safety or efficacy. Instead, it must only establish, among other things, that: (1) the generic drug generally has the same active ingredient as the brand name drug and is a “bio-equivalent” to the innovator drug, *Id.* §355(j)(2)(A)(ii), (iv); and (2) the proposed label of the generic drug is “the same as” that of the innovator drug. *Id.* § 355(j)(2)(A)(v).

Following FDA approval to market a drug, both the innovator and generic manufacturer are subject to continuing obligations to monitor, analyze and report adverse effects associated with the drug. *See* 21 U.S.C. § 355(k); 21 C.F.R. §§ 314.80, 314.81, 314.98. All defendants were required to keep records of and report adverse effects associated with the use of their drug regardless of whether they are “considered drug related.” 21.C.F.R. §§ 314.80(a), (c), 314.98(a). All defendants were also required to review the published literature relating to their drugs. *See Id.* §§ 314.80(b), (d), 314.81(b)(2). Published literature and other information must be reported to the FDA in annual and special reports. *See Id.* § 314.80.

Metoclopramide crosses the blood-brain barrier and causes central nervous system side effects, like tardive dyskinesia. In 1989, Drs. L. Miller and J. Jankovic published a paper where they reviewed the available published scientific literature and identified 1,031 patients with metoclopramide-induced movement disorders and concluded the metoclopramide manufacturers’ estimates of a 1/500 frequency for such disorders was inaccurate.¹ Nevertheless, the 1/500 frequency ratio has been on Reglan/metoclopramide labels since it was inserted by the brand name manufacturer in 1984.

¹ *See* L. Miller and J. Jankovic, “Metoclopramide-Induced Movement Disorders: Clinical Findings With a Review of the Literature,” *Arch. Intern. Med.* 149:2486, 2489 (1989).

By the early 1990s, peer-reviewed medical literature established that metoclopramide's true risk for tardive dyskinesia or extrapyramidal reactions ratio was significantly higher than previously thought. Thus, the risk/benefit analysis for metoclopramide was substantially different than the image presented for FDA approval.

Moreover, two formal epidemiological studies published in peer-reviewed journals in the early 1990s specifically addressed the prevalence of tardive dyskinesia in metoclopramide exposed patients. The article published by Linda Ganzini, et al., entitled "*The Prevalence of Metoclopramide-Induced Tardive Dyskinesia and Acute Extrapyramidal Movement Disorders*," ARCH. INTERN. MED. 153:1469, 1471 (1993). Dr. Ganzini's study found that the frequency of tardive dyskinesia among her patients that were treated with MCP was over 29%, or at a frequency of about 1 in 4 - a prevalence that was 100 times higher than reported in the text of the metoclopramide label. (See *Id.*) In the article, Dr. Ganzini specifically called upon the manufacturers to reevaluate their estimate of risk in the label. A second epidemiological study (closely replicating Ganzini's) found that 27% of patients treated with metoclopramide contracted tardive dyskinesia. (See *Id.* n. 6)

Despite the availability of medical literature, Brand Defendants did not make any changes in their metoclopramide label, and did not call the FDA's attention to the epidemiological data contained in these articles. Wyeth (and Robins, its predecessor) instead chose "no further action" in the face of this literature; Schwarz recognized the problem with the misrepresentations in the label, and attempted to strengthen the label, but never informed any physicians or patients of the change or the existing misunderstandings of the risk.

The deposition testimony of numerous corporate representatives for Brand Defendants highlights the many misrepresentations made by Defendants over the past twenty plus years.

A. Misrepresentations by A. H. Robins

- A previous company (Merck) had initially researched Reglan as a drug in the mid-1970s, but abandoned the research before seeking FDA approval. One of the early animal studies by Merck, included in the Robins written materials, indicated that after a few days use on dogs, the Reglan frequently caused bizarre positions of the animals, posturing, awkward stances, muscle rigidity and tremors. As the drug dose and duration continued past the first few days, the symptoms increased.
- Robins first started investigating the drug Reglan in the mid-1970s, after two other companies had abandoned their efforts to gain approval of the FDA. Robins received limited approval to market Reglan, based on two conditions: 1) the drug would only be sold through hospital pharmacies, so that the duration and use of the drug could be monitored; and 2) that the company would conduct post-approval study of the drug, to track duration and use of the drug after it reached the public market. Neither of these conditions was ever satisfied. Shortly after approval, the limited distribution was removed by the FDA after the pharma industry organizations threatened litigation, and Robins never conducted post-approval study of the drug.
- In 1979, Robins began an “open label” study of Reglan – a study that allowed for a several year examination of people on Reglan to determine affects and side effects from the drug. This study was paid for by Robins, and the actual manuscript of the study was ghost-written by Robins under the name of the lead author (Dr. Taylor, who later admitted he did not write the study, merely allowed Robins to use his name). Although the study initially included several hundred participants, the actual published results only referred to 259 participants, and falsely claimed that none exhibited abnormal movements, and that the study participants were kept on Reglan well past the 12 weeks allowed by the label. When the entire population of patients was evaluated, the results showed that a significant number of users (those that were excluded from the published results) actually did suffer from abnormal movements. Marketing materials prepared by Robins, based on that study, failed to inform doctors of the limitations on use noted in the label (12 weeks), and neglected to mention the true number of patients who suffered abnormal movements.
- Robins tracked prescription habits and trends using a program called Drug Distribution Database, along with outside services such as IMS; from these databases, Robins could track prescription habits of individual doctors with individual medicines and trends in drug usage. This information, had it been evaluated, would have confirmed that doctors were unaware of restrictions on duration of use, and that nearly a third of prescriptions exceeded those restrictions.
- Robins used a “speakers program” where they selected physicians and trained them to be “speakers” on behalf of drug products Robins sold. These physicians were trained in the labels, then allowed to make presentations at seminars, CME speeches, dinner presentations and other “doctor-to-doctor” meetings. As they were not employees of Robins, their opinions “appeared” to be unbiased, and they were also allowed to

promote uses beyond what the FDA could regulate with the label. These selected physicians made presentations literally across the country on behalf of the Robins product, Reglan.

- Robins went bankrupt in 1989, and Wyeth purchased the company out of the bankruptcy. The purchase included a literal transfer of all written materials related to Reglan, including all of the advertising, marketing, regulatory, clinical, medical, FDA correspondence and all other written materials that had been created during the period that Robins owned Reglan.

See Deposition of A.H. Robins Corporate Representative Justin Victoria (Oct 20, 2011);

Deposition taken under protective order, thus it will be mailed to Court for filing under seal.

B. Misrepresentations by Wyeth

- In 1989, Wyeth purchased the drug Reglan out of a bankruptcy of the A.H. Robins Company. As part of their review of the animal, clinical, and published medical articles for Reglan, Wyeth has never been able to ascertain the foundation for the “approximately 1/500 patients” who are expected to suffer acute dystonic reactions. Until they had been involved in many lawsuits, Wyeth never attempted to determine the medical basis for that claim.
- Wyeth subscribes to a number of different prescription tracking companies, such as IMS, which allows them to determine exactly which doctors prescribe Reglan, how often, for what duration and for which patients. These demographics are available to the company, and to their sales people that call on physicians to encourage more frequent and longer prescriptions of Reglan. Despite the availability of this data, Wyeth never attempted to track the usage patterns of Reglan to determine if the label restriction of 12 weeks was being ignored by doctors and patients.
- After Wyeth purchased the product in 1989, their own sales force began “detailing” it, or calling on doctors to encourage the prescription of Reglan. This detailing continued into the mid-1990s, often merely reinforcing habits and beliefs that physicians had held from the days that Robins had been detailing the drug.
- Despite possessing the Robins documents and studies (including the dog studies by Merck, and the ghostwritten study by Taylor), Wyeth never evaluated the misrepresentations advertised to physicians. Even in the face of mounting evidence in the published medical literature of the inaccuracies of the label, Wyeth never undertook a study (or a review of available data in their possession) to determine if the drug was being misused for extended durations or underrepresented the danger of injury. Prior to 1998, Wyeth never even employed an epidemiologist on staff to be able to evaluate such data.

- Internal studies from Wyeth suggest reviews of adverse event data that was to be reported to FDA, and determined that there was no need to revise label warnings – even though a significant number of prescriptions were for extended durations past the 12 weeks allowed, and even though a significant number of patients were reporting abnormal movement disorders. Both of these warning signals of significant label problems were ignored – either for lack of internal ability to understand the signals, or worse, to protect sales.
- Wyeth sold the same active ingredient for Reglan in countries outside the US. In those countries, the drug is accompanied by a label that says, in all caps “DO NOT USE FOR LONG-TERM TREATMENT” and warns that “after a maximum of three days without any acceptable results, consult a doctor”. These same warnings have never appeared in the US label.
- Wyeth knows that, as the brand name company, the entire medical community relies upon their label. Doctors, patients and even generic drug companies rely on the label written and published by the brand name maker for Reglan.
- Wyeth owned Reglan until December 2001. In the 12 years that they owned the drug, they never modified any of the language warning of tardive dyskinesia or regarding the duration of use of the product, despite the dozens of publications in the medical literature questioning the accuracy of the warnings. Wyeth’s medical monitor and safety officer were called upon to review the articles that often described the label as under-representing the danger of TD by a factor of 100. Their review resulted in internal memoranda advising the company that “no further action [was] necessary” – not warning the FDA or physicians, and not enhancing the label’s warnings.

See Depositions of Wyeth corporate representative Paul Minicozzi (August 25 and September 22, 2011), also taken under protective order, and to be filed under seal with the Court.

C. Misrepresentations by Schwarz Pharma

- Schwarz purchased the Reglan NDA from Wyeth on December 27, 2001. Even before acquisition, Schwarz had clearly and immediately identified the problem with long term use causing a high incidence of TD. In fact, at the time they purchased the Reglan NDA from Wyeth, there was a pending written request by FDA to Wyeth requesting Wyeth “to specify the incidence of Tardive Dyskinesia, Parkinson's-like symptoms and Pyramidal Tract Symptoms in the package insert. (If these data are available)” (See Exhibit 7 to Deposition of Schwarz designated corporate representative Donna Multhauf).
- In the pre-purchase evaluation of the USA Reglan product, Schwarz's Vice President of Medical and Regulatory Affairs, Steve Pollock advised “... It is recommended that upon acquisition, [Reglan] go through a thorough safety and labeling review,

updating the labeling if any additional deficiencies or liabilities are seen. The Reglan product will take a fair amount of attention" (See Ex. 1 to Multhauf Deposition)

- Subsequently, two original in-house evaluations followed by several independent research analyses further discerned and confirmed the common practice of long term use and a 10-30% incidence of TD that accompanied such use. In short, confirming that the label was inaccurate and was not warning physicians and patients. (See Multhauf Deposition at pp. 105-108, 189-190, 226-229).
- On November 5, 2003, Sabine Wever, Head of Corporate Drug Safety for Global Schwarz in Germany, requested her American counterpart, Donna Multhauf, to "please urgently work on the update of the Reglan label, especially regarding therapy duration, risk population and neurological side effects including Tardive dyskinesia." (See Ex. 10 to Multhauf Deposition). This "urgent" request from the head of Schwarz worldwide safety was summarily aborted by local American VP, Steve Pollack who wrote in an email that the effort would be too "time consuming." (See Exs. 11 and 45 to Multhauf Deposition).
- Although Wyeth/Schwarz had been specifically asked by FDA to provide TD incidence information in 2001, despite having several internal opinions and consistent information showing a 10-30 % incidence, believed to be higher in the elderly, Schwarz deceived FDA and advised FDA by letter dated October 22, 2002 that "The data necessary to determine these incidence rates is not available, thus SP Inc is not able to provide the additional information." (See Ex. 8 to Multhauf Deposition).
- In February 2004 Schwarz effected a Reglan label change to include bolded language limiting use to 90 days. This language stated: "**THERAPY SHOULD NOT EXCEED 12 WEEKS IN DURATION.**" The language was intended to curb the common practice of long term use of Reglan that led directly to an unreasonably high risk of TD. However, the 2004 Schwarz label revision neither removed the false and misleading 1/500 EPS risk figure nor the additional language suggesting that long term use was approved.
- Most notably, however, although the 2004 label change was clearly an important safety related label change by which the branded manufacturer sought to alter longstanding prescribing practices, Schwarz did **nothing** to disseminate or publicize this important event. (See Multhauf Deposition at pp. 117-140). If a Doctor had wanted to find the Schwarz 2004 revised Reglan label change, he would have to look it up on the company website, as it was never published in the PDR. (See Multhauf Deposition at pp. 193 and 269).
- In 2005, Schwarz became aware through an external review that 30% of Reglan patients received long term treatment with Reglan, exceeding 90 days. (See Ex. 18 to Multhauf Deposition).

- In February of 2005, Schwarz' Brigitte Dehlin, MD circulated a 3 page study\literature review in which she opined, "It is estimated that TD occurs in approximately 15-30% of persons who receive long-term treatment with neuroleptics... Because increasing age is a TD risk factor, the prevalence is around 29% in elderly patients receiving dopamine antagonist treatment for 3 months and 26-67% in chronically treated patients." (See Ex. 23 to Multhauf Deposition). This information was never provided to FDA or incorporated into the Reglan label.
- Also in 2005, Schwarz commissioned yet another study which again revealed that a large number of Reglan patients received treatment in excess of 90 days. As a result, physician education programs, patient "starter kits" with TD risk information provided, letters to physicians advising, and other methods of delivering the long term use message to physicians and patients were proposed/considered; however, none were ever implemented. (See Ex. 25 to Multhauf Deposition; Deposition of Multhauf at pp. 245-250).
- Finally, in 2007 Schwarz further commissioned yet another external report/review entitled "Reglan Situation Analysis" and was again advised that prescribers continued to prescribe Reglan long term and that they rarely advised patients about the common risk of TD. (See Ex. 28 to Multhauf Deposition).
- No further label change was ever made, no publicity of the 2004 label change was ever conducted, none of the risk mitigation efforts were ever implemented and the FDA was never provided the TD risk information they requested in 2001. As a result of the non-actions of Schwarz, tens of thousands of unsuspecting Reglan consumers were put at risk for development of TD.

See Deposition of Schwarz corporate representative Donna Multhauf, taken under protective order, and to be filed under seal with the Court.

As the RLD holder for Reglan, tasked by the FDA with the duty and responsibility of providing a safe, accurate and current label that the generic\ANDA holder manufacturers were required by law to follow and to copy verbatim, it was not only foreseeable but was legally required that ALL manufacturers would follow, copy and rely upon the Brand Defendant's label, which, in turn, would be the exact and only form of the label available to Doctors and\or patients. Following *Mensing*, it has been further established that the generic manufacturers were not legally able to deviate from, or to change, modify or emphasize the RLD label. Schwarz's label

was not only foreseeably relied upon with a high degree of probability; it was legally required to be relied upon with certainty.

As set forth in his Original Complaint, Mrs. Hogue physician prescribed Reglan to treat abdominal pain/digestive problems in 2000, and she continued to take Reglan for approximately the next nine years. (Complaint at ¶22). Mrs. Hogue's use of Reglan, as prescribed, resulted in overexposure to the drugs which have caused her to suffer serious, permanent and disabling injuries, including but not limited to, injuries of or associated with the central nervous and extrapyramidal motor systems, specifically tardive dyskinesia, a severe and often permanent disfiguring neurological movement disorder. (Complaint at ¶30). Had she and her prescribing physicians known of the true dangers of the drug (as was known to Brand Defendants), she never would have taken the drug for such an extended period.

III. ARGUMENT AND AUTHORITIES

A. Ohio Law is Consistent with a Drug Innovator's Liability for its Warnings When the Warnings Accompany a Generic Drug

Whether Brand Defendants actually manufactured the pills that Mrs. Hogue ingested is immaterial to the claims against them. The action of Brand Defendants at issue is their dissemination of false and misleading information, which they knew would be relied upon by the prescribing physician, and directly and proximately caused Mrs. Hogue's injuries. It is not whether Mrs. Hogue actually ingested the Reglan manufactured by them.

In Ohio, the elements of fraud and negligent misrepresentation are very similar. *Martin v. Ohio State Univ. Found.*, 742 N.E.2d 1198 (Ohio Ct. App. 2000). In particular, justifiable reliance is an essential element of both. In describing liability for negligent misrepresentation, the Ohio Supreme Court has written: "One who, in the course of his business, profession or employment, or in any other transaction in which he has a pecuniary interest, supplies false

information for the guidance of others in their business transactions, is subject to liability for pecuniary loss caused to them by their justifiable reliance upon the information, if he fails to exercise reasonable care or competence in obtaining or communicating the information.” *Delman v. Cleveland Hts.*, 534 N.E.2d 835 (Ohio 1989). The elements of fraud are: (a) a representation or, where there is a duty to disclose, concealment of a fact, (b) which is material to the transaction at hand, (c) made falsely, with knowledge of its falsity, or with such utter disregard and recklessness as to whether it is true or false that knowledge may be inferred, (d) with the intent of misleading another into relying upon it, (e) justifiable reliance upon the representation or concealment, and (f) a resulting injury proximately caused by the reliance. *Roberts v. Hagen*, No. 2845-M, 2000 WL 150766 (Ohio Ct. App. Feb. 9, 2000) at *2.

Once again, it is the information that is at issue, not the actual pill consumed. The Ohio authority cited by Brand Defendants fails to take into account the crucial details present in this case. Namely, in this case there are brand name companies that write the label, and a generic manufacturer that is required to use the brand name’s label. At a minimum, Brand Defendants are subject to liability as the information disseminated by each are a required component of the product at issue.

B. Recent Case Law Involving Defendants Adopts Label Misrepresentation Drug Liability

Further, the Ohio authority cited by Defendants pre-dates the recent decisions in *Mensing, Conte v. Wyeth, Inc.*, 168 Cal. App. 4th 89 (2008) and *Kellogg v. Wyeth*, ---F.Supp. 2d---, 2010 WL 5560251, No. 2:07-cv-82 (D. Vt. Oct 20, 2010).

The ruling made several months ago by the Supreme Court in *PLIVA, Inc. v. Mensing*, ___ U.S. ___, 131 S. Ct. 2567 (2011), largely overturned the reasoning cited by defendants, *Foster v. American Home Products Corporation*, 29 F.3d 165 (4th Cir.1994). *Foster* held that a generic

manufacturer of a drug had the ability to change the content of the label that accompanied their drug when it learned of new dangers posed by its use; thus, any claims for a defective label or misrepresentations regarding dangers of the product were to be asserted against the generic manufacturer. As such, the claim did not rest against the brand maker:

As an expert, a manufacturer of generic products is responsible for the accuracy of labels placed on its products. Although generic manufacturers must include the same labeling information as the equivalent name brand drug, *they are also permitted to add or strengthen warnings and delete misleading statements on labels*, even without prior FDA approval.

Id. at 170 (emphasis added).

As a direct result of this ruling, numerous courts in subsequent cases, overwhelmingly trial courts sitting in various states, have followed *Foster's* analysis. The *Foster* analysis was reversed by *Mensing*, which held that the generic manufacturer cannot change the content of the label. The brand name manufacturer is the only company that can change label warnings.

It has now been determined in *Mensing*, contrary to the *Foster* court's suppositions, not only that the CBE provision was unavailable to a generic manufacturer, but also that the FDA itself could not change the content of the labeling of a prescription drug without the consent of the NDA holder.

Brand Defendants, as manufacturers and sellers of the brand name product Reglan, provided information to the medical community and doctors (and to generic manufacturers that merely copy the label) about the uses and side effects of metoclopramide, and they owed a duty to exercise reasonable care to ensure that this information was not inaccurate or misleading. The generic manufacturers of metoclopramide were not allowed to change the content of their labeling to differ from the language appearing in the label of the Brand Defendants – whether accurate or not – according to the *Mensing* decision.

In *Conte* and *Kellogg*, the misrepresentation claims were analyzed properly as negligence claims. Simply put, the *Conte* and *Kellogg* decisions got it right even before the *Mensing* decision, and this court should adopt their analysis in light of *Mensing*.

The California Court of Appeals held in 2008 that Defendant Wyeth owed a duty of care to patients who take a generic version of Reglan pursuant to a prescription written in reliance on the brand name information. *Conte v. Wyeth, supra*, 168 Cal. App. 4th at 107. The court explained that in so deciding,

we are not marking out new territory by recognizing that a defendant who authors and disseminates information about a product manufactured and sold by another may be liable for negligent misrepresentation where the defendant should reasonably expect others to rely on that information and the product causes injury, even though the defendant would not be liable in strict products liability because it did not manufacture or sell the product.

Id. at 102.

More recently, in *Kellogg*, the U.S. District Court for the District of Vermont, recognizing that false information about a prescription drug's effects could cause doctors to make dangerously inappropriate prescribing decisions, issued a similar ruling. The court held that Wyeth owed a general duty of care, and would be liable for injuries proximately caused by its breach, whether or not it manufactured the generic metoclopramide that the plaintiff ingested.

To recognize that a brand name drug manufacturer owes a duty to use reasonable care to avoid causing injury to consumers of the generic bioequivalents of its drugs does not "recognize a new cause of action or enlarge an existing one," *Langle v. Kurkul*, 510 A.2d 1301 (Vt. 1986)] at 1306, an activity inappropriate for a federal district court sitting in diversity to undertake. . . . This Court has simply applied the basic precepts of Vermont's negligence law to ascertain whether a legally cognizable duty exists, and has concluded that it does.

2010 WL 5560251, at *11.

In both *Conte* and *Kellogg*, the court expressly considered the reasoning and assumptions in *Foster* at length, and explicitly rejected them. *Conte*, 168 Cal. App. 4th 107-11; *Kellogg*, 2010

WL 5560251, at *11-*13. The *Foster* decision was wrong, as both courts recognized, because the conduct the plaintiffs asserted to be negligent was the *dissemination* of false information, not the *manufacture or sale* of a product (whether with or without adequate warnings). The courts noted that, in addition, it was perfectly reasonable for a doctor, when prescribing a drug, to rely on what the maker of the brand name drug said about its own product and manifestly predictable that the prescribing doctor's patients would receive and ingest generic versions of the drug made by other companies. *Conte*, 168 Cal App. 4th at 109, 111; *Kellogg*, 2010 WL 5560251, at *13.

In the wake of the *Conte* and *Kellogg* decisions, scholarly commentary has agreed with these holdings. See, generally, Allen Rostron, *Prescription For Fairness: A New Approach to Tort Liability of Brand-Name and Generic Drug Manufacturers*, 60 Duke L.J. 1123, 1127-1128 (2011) (" . . . *Conte* should . . . be seen as the first case in which a court finally got this issue right. The *Conte* court saw through distracting mischaracterizations of the issue that plagued judicial analysis in *Foster* and other past cases.") and 1190 ("*Conte* in fact represents the most careful and sophisticated consideration that any court has given to these difficult issues."); see also Martin A. Ramey, *Conte v. Wyeth: Caveat Innovator and the Case for Perpetual Liability in Drug Labeling*, 4 Pitt. J. Envtl. & Pub. Health L. 73, 77 (2010) ("*Conte* is founded upon traditional tort principles that have been widely accepted for decades [and as such] deserves its fair place in the sun.") and at 103-104, 110-111, and 114 (criticizing *Foster* and its progeny, and advocating shared liability on principles of comparative fault).

Under generally and traditionally accepted principles of law, as recognized in Ohio, Brand Defendants owed a duty to exercise reasonable care in the dissemination of information regarding their drug products in order to avoid causing physical harm to those who relied upon this information—a duty that Brand Defendants breached under the circumstances shown in this

case by failing to exercise due care to ensure that the information relied upon by physicians in writing prescriptions for their drug products provided was not false or misleading.

By actively choosing to become the RLD holders for metoclopramide, Brand Defendants voluntarily undertook a duty to exercise reasonable care to avoid injuring anyone whose physician relied upon the representations made and the content of their labeling in deciding to prescribe the drug metoclopramide, including Mrs. Hogue's physicians. Despite their duties, the Brand Defendants took no action to amend or modify the Reglan label once there was reasonable evidence of an association of a serious health hazard. Further, Defendants either negligently or intentionally distributed false and misleading information into the stream of commerce by their actions, sales, detailing, and by placing the misinformation in the label. The Brand Defendants were aware that this information would be relied upon by physicians in prescribing the drug, and that it would accompany the products sold by generic manufacturers in addition to their own.

Individuals who are harmed by generic metoclopramide dispensed pursuant to a doctor's prescription for Reglan are undoubtedly within the class of individuals who may be seriously injured by a doctor's reliance on false information given to him about a drug's side effects. Moreover, drug companies that make and sell brand name drugs must know, expect, and accept that when they disseminate information about the drug to the medical community, through the Physicians' Desk Reference and any other means, this information will likely be relied upon by doctors when deciding whether to prescribe the drug. As Wyeth and Schwarz were the only entities that disseminated any information about Reglan to prescribing physicians, they may be held accountable for both providing false information to physicians and for failing to correct the misconceptions they created.

Mrs. Hogue, like the plaintiffs in the *Conte* and *Kellogg* cases, asserts that Brand

Defendants' culpability arose from misrepresentations, fraud and negligent action—*i.e.*, carelessly introducing false and misleading information regarding their drugs into the medical community and keeping important safety information from reaching the same individuals—rather than inaction—*e.g.*, failing to provide adequate warnings. The court in *Conte* reasoned as follows:

As the foreseeable risk of physical harm runs to users of both name-brand and generic drugs, so too runs the duty of care, and Wyeth has not persuaded us that consideration of other factors requires a different conclusion Wyeth's *duty of care in disseminating product information* extends to those patients who are injured by generic metoclopramide as a result of prescriptions written in reliance on Wyeth's product information for Reglan.

168 1. App. 4th at 107 (emphasis added).

As remarked in *Kellogg, supra*, quoting *Conte, supra*, “[W]hat is unfair about requiring a [name-brand] defendant to shoulder its share of responsibility for injuries caused, at least in part, by its negligent or intentional dissemination of inaccurate information?” 2010 WL 5560251, at *10. Upon evaluation of the overall basic fairness of imposing the duty, and consideration of all the factors identified, it becomes clear that all of these factors, under the circumstances shown, support the recognition of a duty on the part of Brand Defendants to exercise reasonable care in ensuring the accuracy and truthfulness of the information they provide to the medical community. Further, the breach of that duty justifies the imposition of liability on Brand Defendants for injuries caused by a patient's overexposure to metoclopramide.

When companies such as Brand Defendants develop and disseminate to the medical community information about the effects of their drugs, they have the obligation to exercise reasonable care. Brand Defendants exercised complete control over information they disseminated for years, including the labels of both Reglan and generic metoclopramide. As Professor Ramey suggests, since it is typically the “innovator”—*i.e.*, the company that makes

and markets the brand name version—which has developed and spread the information that doctors actually read and rely on when prescribing the drug, imposing liability on the innovator for injuries due to the doctor's reliance on that information, if it is false, would typically place the economic burden of such injuries on "the party best capable of mitigating that risk." *Caveat Innovator, supra*, 4 Pitt. J. Envtl. & Pub. Health L. at 109.

Imposing a duty to exercise reasonable care would not add appreciably to the burden imposed on the "innovator" already, under products liability law. It would be obliged to provide truthful and accurate information regarding its own product, which is essentially the same as any generic version of the drug that a patient may receive. Since the Brand Defendants are already obligated to exercise due care in the dissemination of information for the benefit of consumers of their own products, ensuring that this information was accurate and not misleading adds no additional responsibility.

Liability on such claims, even when the injuries come about from the ingestion of the generic equivalent of the drug, would not fundamentally undermine the advantages that are meant to be extended to drug companies in order to encourage pharmaceutical innovation. Although the innovator drug company will not, in most instances, have made or sold any generic product the plaintiff ingested and will have gained no economic benefit from that sale, "the basic reality [is] that, for years, an innovator has been able to exclusively market an expensive medication, reaping a handsome return on its investment and, in some cases, billions of dollars of profit" and "earning possibly more from the sale of the brand name drug than the generic manufacturer can ever hope to make." *Caveat Innovator, supra* at 109, 111. As the *Conte* court points out, manufacturers of brand name prescription drugs enjoy several unique, legislatively created advantages, such as a period of patent protection and of market exclusivity and an ability,

due to this period of protection as well as brand name recognition, to charge higher prices for their products. 85 Cal. Rptr. 3d at 110. If these innovators come to share later in liability for injuries caused by their own negligence, that is hardly unfair.

C. The Liability of an Innovator for Products Manufactured by Another Has Long Been Recognized

Finally, the concept that a designer or originator remains liable, under certain conditions, for products manufactured by another has long been recognized. Because a “manufacturer, as well as all suppliers of a product, also has a duty to inform users of hazards associated with the use of its products....[t]here is no reason to distinguish a designer, who has intimate knowledge of a designed product, from a retailer, wholesaler or manufacturer.” *Alm v. Aluminum Co. of America*, 717 S.W.2d 588, 591 (Tex. 1986), citing RESTATEMENT (SECOND) OF TORTS § 388 (1965); additional citation omitted, italic added. Indeed *Alm* has been applied in just these circumstances. A federal court held in a Thimersol case against Eli Lilly that:

It is undisputed that Lilly did not manufacture the thimerosal that was administered to Jordan Easter as part of his vaccine regimen. However, plaintiffs allege that for many years, Lilly, as the original designer of thimerosal, distorted published medical literature and deceived health regulators and physicians about the safety of thimerosal. They further allege that Lilly's misrepresentations were relied upon by physicians, health regulators, and other thimerosal manufacturers which led to the widespread use of thimerosal in vaccines.

Easter v. Aventis Pasteur, Inc., 2004 WL 3104610, 8 (E.D.Tex. 2004). The Court noted that the thimerosal at issue did not deviate from Lilly's original design. *Id.* Indeed, as a bioequivalent, it could not have. Moreover, “Lilly developed the design for thimerosal, used thimerosal in vaccines, licensed thimerosal to other manufacturers, and after its patent expired, knew that other manufacturers had copied its thimerosal design for use in vaccines.” *Id.* Therefore, “Lilly was in the best position to know about the potentially harmful effects of thimerosal, to warn others about them, and even, as plaintiffs allege, to conceal them as well.” *Id.* As here, the Easters

alleged “that ... Lilly promoted thimerosal as being non-toxic while concealing research findings which showed that it was indeed toxic.” This led the Court to conclude that “Lilly, as a designer, has a duty to develop a safe design for thimerosal. Also, Lilly's design of an intimate knowledge about thimerosal also gives rise to a duty to inform users of hazards associated with the use of thimerosal.” *Id.*

The same facts are present here. Brand Defendants, as the innovators and primary manufacturers have an ongoing duty to provide an adequate warning and refrain from disseminating false and misleading information about their product, and to correct misperceptions as soon as possible if patients are being harmed. They have consistently misrepresented the true nature of Reglan for over twenty years. As a result, they should be held accountable for their misrepresentations, negligent and fraudulent acts and omissions.

IV. CONCLUSION

For the reasons cited above, Brand Defendants’ Motion for Summary Judgment should be denied.

Respectfully submitted,

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CERTIFICATE OF SERVICE

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